

REMARKS

Claims 35-38, 40-42, 44-50, 52-54, 56-62, and 67-71 are pending. Claims 1-34, 39, 43, 51, 55, and 63-66 have been cancelled.

Examiner Interview

Applicant respectfully thanks the Examiner for granting a telephonic interview that was conducted on October 22, 2008, and for the courtesy extended during the same.

Claim Rejections - 35 U.S.C. §102(b)

Claims 35-38, 40-42, 44-50, 52-54, 56, 57, 59, and 60 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,665,089 to Dall ("Dall '089").

Dall '089 discloses the use of ladder plate 81, as shown in Fig. 8, in combination with ladder plate 82 for bracing complex fracture 83 with butterfly fragment 84. The end openings of ladder plate 81 contain single-screw fixation means 38, which are screwed to bone. Additionally, as described with reference to Fig. 2, a ladder plate, such as ladder plate 36, may be mounted to bone 30 and secured by cerclage cables 64 passing through holes 48. Each loop of cable 64 is pulled tight and locked in place by crimping respective bridges 42, as shown in Fig. 3.

Applicants respectfully submit that amended independent Claims 35, 54, and 60 are not anticipated by Dall '089, as Dall '089 fails to disclose each and every limitation called for in amended independent Claims 35, 54, and 60. Specifically, each of amended independent Claims 35, 54, and 60 call for an implant for the treatment of bone fractures including, *inter alia*, a main plate adapted to be fixed to a bone and a plate-shaped outrigger element adapted to be fixed to a bone, the implant further comprising a U-shape flexible connection element having a pair of U limbs extending outwardly from a U base, wherein the main plate has at least one pair of first passages and the outrigger element has at least one pair of second passages through which the U arms of the connection element are guidable, wherein, in the assembled state of the implant, the U base is adjacent the outrigger element and the U limbs of the connection element extend outwardly from the outrigger element.

In forming the rejection, the Examiner relies on cerclage cable 64 of Dall '089 as forming the flexible connection element called for in the amended independent claims. However, as shown in the figures of Dall '089, cerclage cable 64 fails to define a U-shaped flexible connection element having a pair of U limbs extending outwardly from a U base, such as shown in Fig. 10 of the present application. In justifying the rejection, the Examiner indicated during the above-identified Examiner interview that the limitation of a "U-shape flexible connection element having a pair of U limbs extending outwardly from a U base" was interpreted as a functional limitation and that cerclage cable 64 of Dall '089 is capable of performing the required function. A functional limitation is a limitation in a claim that "is an attempt to define something by what it does, rather than what it is." MPEP 2173.05(g), Functional Limitations. Nothing in the limitation of a "U-shape flexible connection element having a pair of U limbs extending outwardly from a U base" defines the connection element by what it does. In fact, each element recited in this limitation is clearly structural, i.e., a U-shaped flexible connection element, a pair of U limbs, and a U base. When the language of independent Claims 35, 54, and 60 is interpreted properly, specifically that the limitation of "U-shape flexible connection element having a pair of U limbs extending outwardly from a U base" is interpreted as a structural limitation, there is no disclosure in Dall '089 of a "U-shape flexible connection element having a pair of U limbs extending outwardly from a U base," rendering the rejection of independent Claims 35, 54, and 60 improper.

Moreover, assuming, *arguendo*, that the limitation of a "U-shape flexible connection element having a pair of U limbs extending outwardly from a U base" is a functional limitation, there is no indication in the disclosure of Dall '089, that cerclage cable 64 of Dall '089 could be formed as a "U-shape flexible connection element having a pair of U limbs extending outwardly from a U base" and still function for its intended purpose. In order to make such a determination, one would have to have knowledge of numerous material qualities and physical properties of cerclage cable 64, none of which are disclosed in Dall '089. For example, in order to determine whether cerclage cable 64 of Dall '089 could be formed as a "U-shape flexible connection element having a pair of U limbs extending outwardly from a U base," it would be necessary to know the gauge of cerclage cable 64, the length of cerclage cable 64, the material from which cerclage cable 64 is formed, the process by which the material forming cerclage cable 64 was made, the structure of cerclage cable 64, e.g.,

whether cerclage cable 64 is solid or braided, etc. Without this type of specific information regarding cerclage cable 64, one is incapable of determining whether cerclage cable 64 may be formed as a U-shape flexible connection element having a pair of U limbs extending outwardly from a U base.

In forming the rejection, the Examiner simply concludes that, "Nothing prevents the flexible members of Dall ['089] from being fed in such a manner as described in the present Office Action." Office Action dated June 30, 2008, page 6. However, simply indicating that a references fails to state that a certain construct or condition is rendered impossible does not overcome the lack of disclosure indicating that such a construct or condition is in fact possible. In order to form a proper rejection under 35 U.S.C. §102, each and every element of a claim must be expressly or inherently described in a single prior art reference. *See* MPEP §2131, Anticipation. Thus, even if the limitation of a "U-shape flexible connection element having a pair of U limbs extending outwardly from a U base" is improperly interpreted to be a functional limitation, Dall '089 must contain disclosure sufficient to indicate that cerclage cable 64 is capable of forming a "U-shape flexible connection element having a pair of U limbs extending outwardly from a U base". For at least the reasons set forth above, Dall '089 lacks this disclosure.

Further, assuming, *arguendo*, that cerclage cable 64 could be formed to have a U-shape, Dall '089 fails to disclose a U-shaped flexible connection element having a pair of U limbs extending outwardly from a U base and a main plate having at least one pair of first passages and an outrigger element having at least one pair of second passages through which the U arms of the connection element are guidable, wherein, in the assembled state of the implant, the U base is adjacent the outrigger element and the U arms of the connection element extend outwardly from the outrigger element. Specifically, taking a portion of the cerclage cable 64 of Dall '089 as forming a U base, no where does Dall '089 disclose or suggest positioning a U base adjacent one of ladder plates 81, 82 with *both* of the pair of U limbs extending outwardly from the one of ladder plates 81, 82.

For at least the foregoing reasons, Applicants respectfully submit that amended independent Claims 35, 54, and 60, as well as Claims 36-38, 40-42, 44-50, 52, 53, 56, 57, and 59, which depend therefrom, are not anticipated by Dall '089.

Claims 69-71 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,932,820 to Osman ("Osman '820").

Osman '820 discloses spinal fixation device 10, shown in Fig. 1, including first plate 14 and second plate 16. Fixation device 10 is positioned along a vertebral column adjacent vertebrae 18, 20 which span a bone graft-receiving site 22. First plate 14 includes body portion 20 having openings 32 formed therein for the receipt of fixation screws, which secure first plate 14 to vertebrae 18. First plate 14 also includes male projecting part 36 having opposing legs 42. Legs 42 includes ratchet teeth 38 formed thereon. Similar to first plate 14, second plate 16 includes openings 44 for the receipt of fixation screws, which secure second plate 16 to inferior vertebra 20. Additionally, second plate 16 includes recess 50 configured for receipt of male part 36 of first plate 14. Recess 50 includes ratchet teeth 39, which cooperate with and are complementary shaped to receive ratchet teeth 38 of male part 36. In use, with spinal plates 14, 16 secured to adjacent vertebrae 18, 20, ratchet teeth 38, 39 of plates 14, 16 cooperate to set the spacing between adjacent vertebrae 18, 20. Once secured, plates 14, 16 are then able to move toward one another by the cooperating sloped surfaces of ratchet teeth 38, 39. Thus, if a patient moves in a manner that decreases the distance between vertebrae 18, 20, first and second plates 14, 16 may be advanced toward one another, causing a corresponding advancement of ratchet teeth 38, 39. The interaction of ratchet teeth 38, 39 then prevents plates 14, 16 and, correspondingly, vertebrae 18, 20, from returning to their original positions.

Applicants respectfully submit that independent Claim 69 is not anticipated by Osman '820, as Osman '820 fails to disclose each and every limitation called for in amended independent Claim 69. Specifically, amended independent Claim 69 calls for an implant for the treatment of bone fractures, the implant including, *inter alia*, a main plate adapted to be fixed to a bone having at least one pair of passages formed therein, and a plate-shaped integral outrigger element adapted to be fixed to the bone, wherein, in an assembled state of the implant, the plate-shaped integral outrigger element is arranged offset from the main plate, the integral outrigger element including a flexible connection element having a pair of arms, wherein, after the main plate and the integral outrigger element have been fixedly secured to a static bone, the pair of arms of the flexible connection element may be advanced into the at least one pair of passages of the main plate to connect the main plate and the outrigger element to treat a bone fracture.

In contrast to amended independent Claim 69, legs 42 of plate 14 of Osman '820 are incapable of being advanced into recess 50 of plate 16 after plates 14, 16 have been fixedly secured to a static bone. Specifically, the advancement of ratchet teeth 38, 39 is facilitated by the ability of adjacent vertebrae 18, 20 to move relative to one another. However, if vertebrae 16, 18 were instead static, e.g., were held in a fixed or stationary condition, ratchet teeth 38 of plate 14 could not be advanced into recess 50 of plate 16.

Thus, for the foregoing reasons, Applicant respectfully submits that amended independent Claim 69, as well as Claims 70 and 71 which depend therefrom, are not anticipated by Osman '820.

Claim Rejections - 35 U.S.C. §103(a)

Claims 58, 61, 62, and 67-71 are rejected under 35 U.S.C. § 103(a) as being obvious over Dall '089 in view of WO03/032849 to Tassin ("Tassin '849").

In forming the rejection of Claims 58, 61, 62, 67, and 68, the Examiner relies on Dall '089 as disclosing each and every limitation of independent Claim 35, from which Claims 58, 61, 62, 67, and 68 depend. However, for at least the reasons set forth above with respect to independent Claim 35, Dall '089 fails to disclose or suggest each and every limitation of independent Claim 35. The Examiner's additional citation of Tassin '849 fails to overcome this deficiency, as neither Dall '089 nor Tassin '849, either alone or in combination, disclose an implant for the treatment of bone fractures including, *inter alia*, a main plate adapted to be fixed to a bone and a plate-shaped outrigger element adapted to be fixed to a bone, the implant further comprising a U-shape flexible connection element having a pair of U limbs extending outwardly from a U base, wherein the main plate has at least one pair of first passages and the outrigger element has at least one pair of second passages through which the U arms of the connection element are guidable, wherein, in the assembled state of the implant, the U base is adjacent the outrigger element and the U limbs of the connection element extend outwardly from the outrigger element, as called for in independent Claim 35.

Thus, for at least the foregoing reasons, Applicants respectfully submit that Claims 58, 61, 62, 67, and 68, which depend from independent Claim 35, are not obvious over Dall '089 in view of Tassin '849.

In forming the rejection of amended independent Claim 69, as well as Claims 70 and 71 which depend therefrom, the Examiner relies on Dall '089 as disclosing each and every limitation of amended independent Claim 69, except for the integral outrigger element. Thus, the Examiner relies on Dall '089 for disclosing a flexible connection element having a pair of arms. However, Dall '089 fails to disclose a flexible connection element having a pair of arms. In contrast, Dall '089 discloses a connection element in the form of cerclage cable 64, which lacks a pair of arms. The Examiner's additional citation of Tassin '849 fails to overcome this deficiency, as neither Dall '089 nor Tassin '849 disclose or suggest, either alone or in combination, disclose an implant for the treatment of bone fractures including, *inter alia*, an implant comprising a main plate adapted to be fixed to a bone and having at least one pair of passages formed therein, a plate-shaped integral outrigger element adapted to be fixed to the bone, the integral outrigger element including a flexible connection having a pair of arms, wherein, after the main plate and the integral outrigger element have been fixedly secured to a static bone, the pair of arms of the flexible connection element may be advanced into the at least one pair of passages of the main plate to connect the main plate and the outrigger element to treat a bone fracture, as called for in amended independent Claim 69.

Thus, for at least the forgoing reasons, Applicants respectfully submit that amended independent Claim 69, as well as Claims 70 and 71, which depend therefrom, are not obvious over Dall '089 in view of Tassin '849.

Conclusion

It is believed that the above represents a complete response to the Official Action and reconsideration is requested. Specifically, Applicants respectfully submit that the application is in condition for allowance and respectfully requests allowance thereof.

In the event Applicants have overlooked the need for an additional extension of time, payment of fee, or additional payment of fee, Applicants hereby petition therefor and authorize that any charges be made to Deposit Account No. 02-0385, Baker & Daniels.

Should the Examiner have any further questions regarding any of the foregoing, he is respectfully invited to telephone the undersigned at 260-424-8000.

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Respectfully submitted,



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December 1, 2008

Date